MAY - 1 2001

K010316 1/3

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the CoolTouch "Varia' and "Varia-II" laser systems is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92 and 21 CFR § 807.93 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) Summary.

Applicant: CoolTouch Corporation

Address: 9085 Foothills Blvd.
Roseville, CA 95747

Company Contact: Donald V. Johnson
Director, Regulatory & Quality Affairs

Telephone: (916) 677-1912
(916) 677-1901 (FAX)

Date Summary Prepared: February 1, 2001

Device Name: CoolTouch Corporation Model "Varia" and "Varia-II" Nd:YAG Surgical Laser Systems

Common Name: Laser Instrument, Surgical Laser System and Accessories

Classification Name: Instrument, Surgical, Powered Laser
21 CFR § 878.4810
Product Code: GEX

Predicate Device: "Athos" Long Pulse Nd:YAG Laser

Device Description: The CoolTouch Corporation CoolTouch "Varia" and "Varia-II" Nd:YAG Surgical Lasers are lasers producing emissions at 1064nm. The lasers consist of several interconnected sections: the *cabinet*, which houses the power supply, cooling system, microcontroller, and the laser head, the *fiber optics*, and the *handpiece*. The systems provide safety features that are designed to protect the user and patient from high voltages and laser emissions.

Intended Use/Indications:

The soft tissue applications are for the coagulation, photocoagulation, incision/excision, ablation, and vaporization of soft tissues including skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Dermatology: Hair removal (destruction of hair follicles) in all skin types and for soft tissue applications. In addition to the tissue types cited, pigmented lesions to reduce lesion size; for patients with lesions that would potentially benefit from aggressive treatment; for patients with lesions that have not responded to other laser treatments. For coagulation and hemostasis of vascular lesions.

Endoscopic/Laparoscopic General Surgery: Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in endoscopic, laparoscopic surgery applications, including but not limited to cholecystectomy, appendectomy, vagotomy, and pyloromyotomy.

Gastroenterology: Tissue ablation and hemostasis in the GI tract; esophageal neoplastic obstructions including squamous cell carcinoma and adenocarcinoma; GI hemostasis; including varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, stomal ulcers, non-bleeding ulcers, gastric erosions, GI tissue ablation, including benign and malignant neoplasms, angiodysplasia; polyps, ulcer, colitis, and hemorrhoids.

General Surgery: Soft tissue in general surgery applications, skin incisions, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, lesions, tissue ablation, vessel coagulation.

Gynecology: Treatment of menorrhagia by photocoagulation of the endometrial lining of the uterus, ablation of endometrial implants and/or peritoneal adhesions, soft tissue excision procedures such as conization of the cervix, intra-uterine gynecologic procedures where cutting, ablation and/or vessel coagulation may be indicated including submucous fibroids, benign endometrial polyps, uterine spetum.

Head and Neck/Otorhinolaryngology (ENT): Coagulation, photocoagulation, incision/excision, ablation, and vaporization of soft tissue.

Hemostasis during surgery: Adjunctive coagulation and hemostasis (control of bleeding) during surgery (endoscopic, laparoscopic, and open procedures).

Neurosurgery: Hemostasis of pituitary tumor, meningioma, hemagioblastoma, AVMs, glioma, glioblastoma, astrocytoma, oligodendroglioma.

Oculoplastics: Incision, excision, vaporization, ablation, and coagulation of soft tissues in oculoplastic procedures such as operations on the lacrimal system, operation on the eyelids, removal of biopsy or orbital tumors, enucleation of the eyeball, exteneration of orbital contents.

Orthopedics: Incision, excision, cutting, ablation and/or hemostasis of intra-articular tissue in orthopedic surgical and arthoscopic applications.

Plastic Surgery: Incision, excision, cutting, coagulation, and vaporization of soft tissue.

Pulmonary/Thoracic Surgery: Palliative treatment of benign and malignant pulmonary airway obstructions including squamous cell carcinoma, adenocarcinoma, carcinoid, benign tumors, granulomas, and benign strictures.

Thoracic Surgery: Incision, excision, cutting, coagulation, and vaporization of soft tissue, including lung tissue, in thoracic applications including but not limited to isolation of vessels for endarterectomy and/or by-pass grafts, wedge resections, thoractomy, formation of pacemaker pockets.

Urology: All applications including superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures, and lesions of the external genitalia (including condyloma accuminata).

Performance Standards:

The CoolTouch "Varia" and "Varia-II" laser systems comply with the appropriate sections of 21 CFR §1010 and 21 CFR § 1040.

Substantial Equivalence Statement:

Based on the information in the premarket notification, the CoolTouch Corporation believes that the "Varia" and "Varia-II" Nd:YAG laser systems are substantially equivalent to the cited legally marketed predicate device for the indications requested.

February 1, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2001

Mr. Donald V. Johnson
Director, Regulatory and Quality Affairs
CoolTouch Corporation
9085 Foothills Boulevard
Roseville, California 95747

Re: K010316
Trade/Device Name: CoolTouch Varia and Varia-II Nd:YAG:Laser Systems
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: February 1, 2001
Received: February 2, 2001

Dear Mr. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K010316

Device Name: CoolTouch Varia and Varia-II Nd:YAG Laser Systems

Indications for Use Statement:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010316

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Indications for Use Statement, Page 2

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